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09/852,053	05/10/2001	Stephan Berens	P 280248 000091 BT	3782

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EXAMINER

FRONDA, CHRISTIAN L

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 12/17/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/852,053

Applicant(s)
Berens et al.

Examiner
Christian L. Fronda

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1652



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above, claim(s) 9-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 8 and 9 6) ☐ Other:

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DETAILED ACTION

Election/Restriction

1. Applicants' election without traverse of Group I, claims 1-8, in Paper No. 12 is acknowledged. Claims 11-15 and SEQ ID NO: 1 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. The requirement is still deemed proper for reasons of record and is therefore made FINAL.
2. Claims 1-8 are under consideration in this Office Action.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
4. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.
The claimed invention encompass any genetically modified *Corynebacterium glutamicum* strain having any genetic modification of the *secD* gene, *secF* gene, or "respective homologous sequences"; any genetically modified *Corynebacterium glutamicum* strain having any mutation, deletion, insertion, or rearrangement to the *secD* gene, *secF* gene, or their respective promoters; any genetically modified *Corynebacterium glutamicum* strain having any genetic modification of the *secD* gene, *secF* gene, or "respective homologous sequences" and further containing any heterologous gene which enables the strain to use any external energy source not used by the wild type *Corynebacterium glutamicum* or enables the strain to produce any substance which is a product of the heterologous gene. The specification, however, only provides the following representative species encompassed by the invention: a *Corynebacterium glutamicum* strain transformed with an inactivated *secD* gene consisting of nucleotides 1200-1809 of SEQ ID NO:1; a *Corynebacterium glutamicum* strain transformed with SEQ ID NO: 1 which encodes the SecD protein or SEQ ID NO: 2 which encodes the SecF protein; and a *Corynebacterium*

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glutamicum strain transformed with SEQ ID NO: 1 which encodes the SecD protein, SEQ ID NO: 2 which encodes the SecF protein, and amylase gene.

The specification does not provide a written description of any genetically modified *Corynebacterium glutamicum* strain having any genetic modification of the *secD* gene, *secF* gene, or "respective homologous sequences"; any genetically modified *Corynebacterium glutamicum* strain having any mutation, deletion, insertion, or rearrangement to the *secD* gene, *secF* gene, or their respective promoters; any genetically modified *Corynebacterium glutamicum* strain having any genetic modification of the *secD* gene, *secF* gene, or "respective homologous sequences" and further containing any heterologous gene which enables the strain to use any external energy source not used by the wild type *Corynebacterium glutamicum* or enables the strain to produce any substance which is a product of the heterologous gene.

Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

5. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated *Corynebacterium glutamicum* host cell transformed with an inactivated *secD* gene consisting of nucleotides 1200-1809 of SEQ ID NO:1, a isolated *Corynebacterium glutamicum* host cell transformed with a heterologous nucleic acid comprising the nucleotide sequence of SEQ ID NO: 1 which encodes the SecD protein or the nucleotide sequence of SEQ ID NO: 2 which encodes the SecD protein, and a *Corynebacterium glutamicum* strain transformed with SEQ ID NO: 1 which encodes the SecD protein, SEQ ID NO: 2 which encodes the SecF protein, and amylase gene; does not reasonably provide enablement for any other embodiment.

Factors to be considered in determining whether undue experimentation is required, are summarized In re Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claims encompass any genetically modified *Corynebacterium glutamicum* strain having any genetic modification of the *secD* gene, *secF* gene, or "respective homologous sequences"; any genetically modified *Corynebacterium glutamicum* strain having any mutation, deletion, insertion, or rearrangement to the *secD* gene, *secF* gene, or their respective promoters; any genetically modified *Corynebacterium glutamicum* strain having any genetic modification of the *secD* gene, *secF* gene, or "respective homologous sequences" and further containing any heterologous gene which enables the strain to use any

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external energy source not used by the wild type *Corynebacterium glutamicum* or enables the strain to produce any substance which is a product of the heterologous gene.

The specification provides guidance and examples for making an isolated *Corynebacterium glutamicum* host cell transformed with an inactivated *secD* gene consisting of nucleotides 1200-1809 of SEQ ID NO:1, a isolated *Corynebacterium glutamicum* host cell transformed with a heterologous nucleic acid comprising the nucleotide sequence of SEQ ID NO: 1 which encodes the SecD protein or the nucleotide sequence of SEQ ID NO: 2 which encodes the SecD protein, and a *Corynebacterium glutamicum* strain transformed with SEQ ID NO: 1 which encodes the SecD protein, SEQ ID NO: 2 which encodes the SecF protein, and amylase gene.

However, the specification does not teach any genetic modification of the *secD* gene, *secF* gene, or "respective homologous sequences"; any mutation, deletion, insertion, or rearrangement to the *secD* gene, *secF* gene, or their respective promoters; or any heterologous gene which enables the strain to use any external energy source not used by the wild type *Corynebacterium glutamicum* or enables the strain to produce any substance which is a product of the heterologous gene.

The standard for meeting the enablement requirement is whether one of skill in the art can make the invention without undue experimentation. The amount of experimentation to make the claimed genetically modified *Corynebacterium glutamicum* is enormous and entails searching for the "respective homologous sequences" of the *secD* gene and *secF* gene; deletion, insertion, or rearrangement of any nucleotide(s) of the *secD* gene, *secF* gene, or their respective promoters to obtain the desired property; and searching for any heterologous gene which enables the strain to use any external energy source not used by the wild type *Corynebacterium glutamicum* or enables the strain to produce any substance which is a product of the heterologous gene.

Since the specification does not provide guidance for any genetic modification of the *secD* gene, *secF* gene, or "respective homologous sequences", any mutation, deletion, insertion, or rearrangement to the *secD* gene, *secF* gene, or their respective promoters, or any heterologous gene which enables the strain to use any external energy source not used by the wild type *Corynebacterium glutamicum* or enables the strain to produce any substance which is a product of the heterologous gene; searching for the "respective homologous sequences" of the *secD* gene and *secF* gene, deletion, insertion, or rearrangement of any nucleotide(s) of the *secD* gene, *secF* gene, or their respective promoters to obtain the desired property, and searching for any heterologous gene which enables the strain to use any external energy source not used by the wild type *Corynebacterium glutamicum* or enables the strain to produce any substance which is a product of the heterologous gene is well outside the realm of routine experimentation.

Predictability in the art of success is extremely low since no information is provided by the specification other than an isolated *Corynebacterium glutamicum* host cell transformed with

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an inactivated *secD* gene consisting of nucleotides 1200-1809 of SEQ ID NO:1, a isolated *Corynebacterium glutamicum* host cell transformed with a heterologous nucleic acid comprising the nucleotide sequence of SEQ ID NO: 1 which encodes the SecD protein or the nucleotide sequence of SEQ ID NO: 2 which encodes the SecD protein, and a *Corynebacterium glutamicum* strain transformed with SEQ ID NO: 1 which encodes the SecD protein, SEQ ID NO: 2 which encodes the SecF protein, and amylase gene

The Examiner finds that one skilled in the art would require additional guidance, such as information regarding the specific nucleotide sequence of the "respective homologous sequences" of *secD* gene and *secF* gene. Without such a guidance, the experimentation left to those skilled in the art is undue.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 the phrase "characterized in that genetical modification concerns at least one of the genes *secD* and *secF* " is vague and indefinite because all the specific genetic modifications are not known and not defined in the specification. Claims 2-8 which depend from claim 1 is also rejected because they do not correct the defect of claim 1.

In claim 2 the phrase "respective homologous sequences" renders the claim vague and indefinite because the specific nucleotide sequences of the "respective homologous sequences" are not known and defined in the specification and it is not known when nucleotide sequences are or are not "respective homologous sequences".

Claim 3 is vague and indefinite because it is not known whether the recited limitations are directed to the *secD* and *secF* genes or to any other genes and it is not known what specific nucleotides are deleted, inserted, mutated, or rearranged.

Claim 8 is vague and indefinite because the claimed substance which is the "product of the claimed heterologous gene or is produced by this heterologous gene product" is not known and defined in the specification.


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Conclusion

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. The fax phone number for this Group is (703)308-0294. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

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